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510K Summary

1. DATE PREPARED

NOV - 8 2006

December 10, 2005

2. SPONSOR INFORMATION

SensaCare Ltd.
Chris Chan
Room 1312, Sterling Centre, 11 Cheung Yue Street, Kowloon, HongKong
Tel : 852-3571-8332
Fax :852-3571-8363
Email : chris@sensacare.com

3. DEVICE NAME

Proprietary Name : SensaCare SAW-102 Wrist Digital Blood Pressure Monitor

Common/Usual Name : Blood Pressure Monitor

Classification Name : Non-invasive Blood Pressure Measurement System
21CFR 870-1130, class II, 74DXN

4. DEVICE DESCRIPTION AND INTENDED USE

The SensaCare SAW-102 Wrist Digital Blood Pressure Monitor is intended for use by adults for measuring the systolic and diastolic blood pressure and pulse rate.

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5. PREDICATED DEVICE

It is substantially equivalent to the following device :
A&D UB-328 FDA 510K K040229, issued on March 19, 2004

6. TECHNOLOGICAL CHARACTERISTECS

SAW-102 uses an inflated cuff which is wrapped around the upper wrist. The cuff is inflated automatically by the air pump. The systolic and diastolic blood pressures are determined by oscillometric method. The deflation rate is controlled by a preset mechanical valve at a constant rate. The pressure of the cuff is completely released automatically at the end of the measurement. At the same time, the measurements are displayed on the LCD display for one minute. After one minute without operation, SAW-102 turns off automatically.
SAW-102 measures blood pressure and pulse rate even when an irregular heartbeat occurs.

7. DEVICE TESTING

Extensive functional and performance testing , and biocompatibility testing were conducted to assess the safety and effectiveness of the SensaCare SAW-102 Wrist Digital Blood Pressure Monitor . All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2006

SensaCare Ltd.
c/o Mr. Marc M. Mouser
Senior Project Engineer, Program Reviewer
Underwriters Laboratories Inc.
2600 NW Lake Road
Camas, WA 98607

Re: K061935
Trade Name: The SensaCare SAW-102 Wrist Digital Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 24, 2006
Received: October 26, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061935

Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

The SensaCare SAW-102 Wrist Digital Blood Pressure Monitor is a hand held battery operated wrist type blood pressure monitor which is intended for use by adults for measuring the systolic and diastolic blood pressure and pulse rate. The measurement is by the oscillometric method wherein a cuff is placed on the limb and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced. The measurement result is shown on a LCD panel in the monitor. The measuring ranges are (1) systolic pressure : 30 to 280 mmHg (2) diastolic pressure : 20 to 255 mmHg (3) heart rate : 20 to 255 times/minutes.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061935